

## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau(43) International Publication Date  
12 August 2010 (12.08.2010)(10) International Publication Number  
**WO 2010/091356 A1**(51) International Patent Classification:  
*A61M 5/00* (2006.01)

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(21) International Application Number:  
PCT/US2010/023491(22) International Filing Date:  
8 February 2010 (08.02.2010)(25) Filing Language:  
English(26) Publication Language:  
English(30) Priority Data:  
61/150,751 7 February 2009 (07.02.2009) US  
61/286,649 15 December 2009 (15.12.2009) US(71) Applicant (for all designated States except US): **MERIT MEDICAL SYSTEMS, INC.** [US/US]; 1600 West Merit Parkway, South Jordan, UT 84095 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **LAMPROPOULOS, Fred P.** [US/US]; 5497 Walker Estates Circle, Salt Lake City, UT 84117 (US). **SNOW, Jeremy W.** [US/US]; 3392 Canyon Meadow Drive, South Jordan, UT 84095 (US).(74) Agent: **BENSON, Ryan D.**; STOEL RIVES LLP, 201 So. Main Street, Suite 1100, One Utah Center, Salt Lake City, UT 84111 (US).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— with international search report (Art. 21(3))

(54) Title: VALVED CONNECTOR

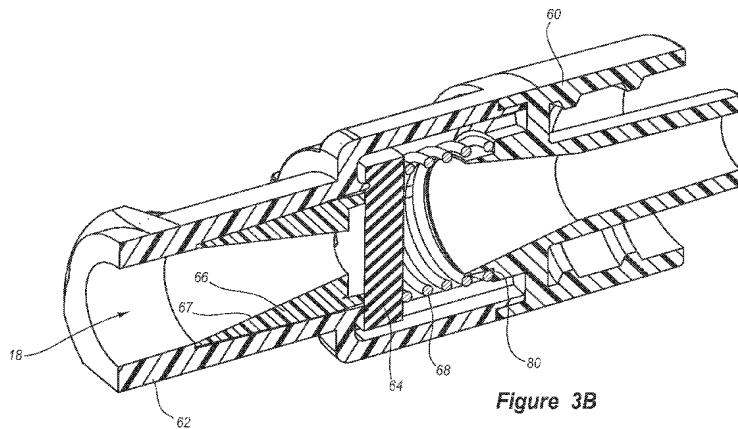


Figure 3B

(57) **Abstract:** A valved connector configured to control the leakage of bodily fluid from within a patient. Valved connector includes a seal positioned within a lumen of the body of the valved connector. Distal end of the valved connector is adapted to permit access to, or coupling of an apparatus, which is placed in fluid communication with the volume of bodily fluid. Proximal end is adapted to be threadably coupled to a secondary device. Needleless connector valve being configured to be openable by a dilator or post of an apparatus which is connected to the proximal end of the needleless connector. In the event that a luer coupler or other secondary apparatus is not available, a needle, cannula, trocar, or other instrument can be threaded through the main lumen of the valved connector opening the valve and allowing the passage of fluid directly through the needle, trocar, cannula, or other instrument.

# VALVED CONNECTOR

## BACKGROUND OF THE INVENTION

### Field of the Invention

**[0001]** The present invention relates to a valved connector which is configured to be placed in fluid communication with a volume of bodily fluid within the body of the patient. In more particular, the present invention relates to a valved connector, which is adapted to allow the passage of bodily fluids from a patient to the external environment utilizing one or both of a threaded connector and a needle or cannula positioned within the lumen of the valved connector.

### Relevant Technology

**[0002]** Valved connectors have been utilized to control the passage of fluid from within a bodily cavity of a patient to the external environment. Oftentimes in modern medicine, a volume of fluid will collect within the tissue or other location within a patient's body. Additionally, at times it is desirable to control the flow of blood, or urine when a particular patient access site is accessed. In such situations, a practitioner can use a connector which has an incorporated valve to limit the undesired flow of fluids from the patient at inopportune times.

**[0003]** One of the deficiencies of currently utilized connectors is that most connectors either allow the unrestricted flow of fluids, or alternatively the connector is cumbersome to use. When a volume of bodily fluid within a patient is accessed, some valved connectors will allow the largely unrestricted passage of fluid until the proximal end of the connector is coupled to a secondary device. Alternatively, some connectors require complicated and cumbersome movement of the stop cock handle or other secondary apparatus to control the passage of fluid through the connector.

**[0004]** Valved connectors are typically configured such that only one of a variety of different types of mechanisms can be utilized to permit flow of fluid. For example, one such apparatus may utilize only a stop cock to control the passage of fluid through the connector. A secondary device, may only allow a needle, trocar or other elongate instrument to permit the passage of fluid. Yet another apparatus may allow a luer-type connector to actuate the passage of fluid. Additionally, valved connectors are typically not configured to allow the introduction of the guide wire through the connector. In the event that a guide wire is positioned within the patient, a connector

cannot be threaded over the guide wire. As a result, fluid communication with the volume of bodily fluid is not permitted until the guide wire has been removed and a secondary apparatus is utilized.

**[0005]** Such valved connector apparatus are often cumbersome, non-intuitive, and complicated to use, limiting the types and variety of surgical or interventional procedures with which such connectors can be utilized. For example, in some instances, once the connector is in fluid communication with the volume of bodily fluid, a stop cock is turned to an open or closed position as desired to control the passage of fluid through a side tubing. Subsequently, a practitioner can insert a needle directly through the lumen of the connector to permit the passage of fluids out of the needle. However, once the needle has been positioned through the apparatus, the stop cock handle can no longer be turned without removal of the needle or other instrument. Other valved connector may permit the opening of the valve of the connector utilizing a luer fitting with a secondary device. However, such valved connectors are not configured to allow the use of a needle to open the valve in the event that a luer connector is not desired or is unavailable.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0006]** Fig. 1A is a front perspective view of a valved connector.

**[0007]** Fig. 1B is a front perspective view of a valved connector illustrating an access apparatus to which the valved connector can be utilized.

**[0008]** Fig. 1C is a front perspective view of a valved connector illustrating coupling of the valved connector to the access apparatus of Figure 1B and a needle apparatus.

**[0009]** Fig. 1D is a front perspective view of a valved connector illustrating coupling of the valved connector to the access apparatus of Figure 1B and to the needle apparatus of Figure 1C and insertion of the access device into a patient.

**[0010]** Fig. 1E is a front perspective view of a valved connector illustrating an access device positioned within a patient.

**[0011]** Fig. 1F is a front perspective view of a valved connector illustrating an access device positioned in a patient and a drainage apparatus coupled to the valved connector.

**[0012]** Fig. 2 is an partial exploded component view of the valved connector of Figure 1A.

**[0013]** Figs. 3A and 3B are cross-sectional views of the valved connector illustrating the juxtaposition of the internal components of the valved connector of Figure 1B.

**[0014]** Fig. 4 is a cross-sectional side view of the valved connector illustrating the manner in which a seal engagement apparatus can be utilized to open the seal of the valved connector.

**[0015]** Fig. 5 is a cross-sectional side view of the valved connector illustrating the manner in which a needle, catheter or cannula can cause opening of the seal of the valved connector.

**[0016]** Fig. 6A is a cross-sectional perspective view of an integral component having a valved hemostasis seal component according to one aspect of the present invention.

**[0017]** Fig. 6B is a cross-sectional perspective view of a integral component of Figure 6A illustrating the use of a needle apparatus according to one aspect of the present invention.

**[0018]** Fig. 7A is a side perspective view of a valved connector according to one illustrative aspect of the present invention.

**[0019]** Fig. 7B is a cross-sectional view of a valved connector according to one illustrative aspect of the present invention.

#### BRIEF SUMMARY OF THE INVENTION

**[0020]** The present apparatus is directed to a valved connector configured to be placed in fluid communication with a volume of bodily fluid within a patient. The valved connector is adapted to selectively permit the passage of fluid from a volume of fluid within the patient to a location external to the patient. The valved connector can be coupled with a catheter or other secondary access device which is positioned within the bodily fluid within the patient. In another embodiment, the catheter tip or micropuncture-type apparatus is integrally coupled to the valved connector with the valved connector being positioned in the hub of the assembly.

**[0021]** According to one embodiment of the present invention, the valved connector includes a seal positioned within a lumen of the body of the valved connector. The distal end of the valved connector is adapted to permit access to, or coupling of a secondary apparatus, which is placed in fluid communication with the volume of bodily fluid. A proximal end is adapted to be threadably coupled to a

secondary device. When the proximal end is threadably coupled or otherwise engaged by the secondary device, a seal engagement apparatus positioned within the proximal end of the valved connector engages the valve allowing the passage of fluid through the lumen of the valved connector. In the event that a luer coupler or other secondary apparatus is not available, a needle, cannula, trocar, or other instrument can be threaded through the main lumen of the valved connector opening the valve and allowing the passage of fluid directly through the needle, trocar, cannula, or other instrument.

**[0022]** Additional aspects and advantages will be apparent from the following detailed description of preferred embodiments, which proceeds with reference to the accompanying drawings.

#### DETAILED DESCRIPTION

**[0023]** The present apparatus is directed to a valved connector configured to be placed in fluid communication with a volume of bodily fluid within a patient. The valved connector is adapted to selectively permit the passage of fluid from a volume of fluid within the patient to a location external to the patient. The valved connector can be coupled with a catheter or other secondary access device which is positioned within the bodily fluid within the patient. In another embodiment, the catheter tip or micropuncture-type apparatus is integrally coupled to the valved connector with the valved connector being positioned in the hub of the assembly.

**[0024]** According to one embodiment of the present invention, the valved connector includes a seal positioned within a lumen of the body of the valved connector. The distal end of the valved connector is adapted to permit access to, or coupling of a secondary apparatus, which is placed in fluid communication with the volume of bodily fluid. A proximal end is adapted to be threadably coupled to a secondary device. When the proximal end is threadably coupled or otherwise engaged by the secondary device, a seal engagement apparatus positioned within the proximal end of the valved connector engages the valve allowing the passage of fluid through the lumen of the valved connector. In the event that a luer coupler or other secondary apparatus is not available, a needle, cannula, trocar, or other instrument can be threaded through the main lumen of the valved connector opening the valve and allowing the passage of fluid directly through the needle, trocar, cannula, or other instrument.

**[0025]** Figure 1 is a perspective view of a valved connector 10 according to one embodiment of the present invention. In the illustrated embodiment, valved connector 10 is adapted to be utilized with a catheter or other instrument which is positioned within an access site which is connected to a volume of bodily fluid within a patient. The volume of bodily fluid can be a volume of fluid that is undesirable and is to be drained from the patient. Alternatively, the volume of fluid can be a volume of urine within the patient's bladder or other urinary tract location, blood from the patient's vasculature, or any other area where fluid is positioned within the patient. In some embodiments, the volume of fluid is not desired to be drained but rather retained within the patient and the valve apparatus is adapted to allow desired instruments or other procedures to be performed while maintaining hemostasis.

**[0026]** In the illustrated embodiment, valved connector 10 comprises a body 12, a male connector 16, a female connector 14, and a main lumen 18. In the illustrated embodiment, female connector 14 is positioned on the distal end of valved connector 10. In the embodiment, female connector 14, is connected to a catheter, or other access device inserted into the patient. A valved connector 12 is positioned within body 12 of valved connector 10. Main lumen 18 is threaded through body 12 allowing passage of fluid from the distal end of valved connector 10 to the proximal end of valved connector 10. In the illustrated embodiment, a male connector 16 is positioned on the proximal end of the valved connector 10. Male connector 16 is adapted to be connected with a threaded coupler of a secondary device which is to be connected to valved connector 10. Such secondary device will typically include a post which extends into the main lumen on the proximal end of valved connector 10. The post of the secondary device is adapted to engage a seal engagement apparatus which selectively opens the seal to permit the passage of fluids when the secondary device is coupled to valved connector 10.

**[0027]** Valved connector 10 is also adapted to allow a needle, cannula, or other implement to be passed through main lumen 18. The configuration of the seal engagement apparatus (not shown) and valve (not shown) allows not only the passage of the instrument, but also the passage of fluid through the needle. The configuration permits the passage of fluid from the distal end of valved connector 10 to the proximal end of valved connector 10.

**[0028]** Figure 1B is a perspective view of valved connector 10 and an access apparatus 20 to be utilized in connection with valved connector 10. In the illustrated embodiment, valved connector 10 can be secured to access apparatus either before or after the access procedure in which a distal end of access apparatus 20 is positioned within the patient. In the illustrated embodiment, access apparatus 20 comprises a catheter 22, a hub 24, and a male luer connector 26. Male luer connector 26 is threadably coupled to female connector 14 of valved connector 10. In a typical procedure, once access apparatus 20 is secured to valved connector 10, catheter 22 is positioned in fluid communication with the main lumen 18 of valved connector 10.

**[0029]** As will be appreciated by those skilled in the art, a variety of types and configurations of access apparatus can be utilized in connection with valved connector 10. For example, in one embodiment, valved connector 10 is secured to an access apparatus not having a threaded connector. In another embodiment, valved connector 10 is secured to a catheter, tubing, or other apparatus. In yet another embodiment, valved connector 10 is adapted to be secured to an apparatus that is not directly in fluid communication with the volume of bodily fluid within a patient, but is instead connected to a secondary apparatus that is positioned outside of the patient's body. In yet another embodiment, the valved connector is utilized to control the flow of fluid from one location to another location. For example, valved connector can be utilized with an infuse bag or medical tubing which is not in communication with a patient's body.

**[0030]** Figure 1C is a perspective view of valved connector 10, depicting securing of valved connector 10 to access apparatus 20. In the illustrated embodiment, a needle apparatus 30 is shown. Needle apparatus 30 can be utilized to provide additional stiffness to catheter 22 during an insertion procedure. In the illustrated embodiment, a patient 40 is depicted. Patient 40 has a volume of fluid 42 positioned within the patient's body, which is to be accessed and/or drained from the patient. In the illustrated embodiment, patient tissue 44 and skin 46 are depicted in connection with patient 40.

**[0031]** Needle 30 is adapted to be threaded from the proximal end of valved connector 10. A needle tip 33 is introduced into main lumen 18 at the portion of main lumen 18 associated with male connector 16. Needle tip 33 is advanced such

that it passes through body 12 of valved connector and into hub 24 of access apparatus 20. In this manner, needle cannula 32 is positioned through body 12 of valved connector such that needle cannula 32 is threaded through the valve positioned within body 12 of valved connector. The needle 30 is further advanced until needle tip 33 is positioned adjacent a catheter tip 28 of valved connector 10. According to one embodiment of the present invention, the length of needle cannula 32 is configured such that hub 34 of needle 30 is positioned adjacent male connector 16 of valved connector 10. In this manner, needle tip 33 is positioned exactly adjacent catheter tip 28 providing the sufficient rigidity and stiffness to catheter tip 28 along the entire length of catheter 22 such that catheter tip 28. In this manner, catheter tip 28 can be advanced into the volume of fluid 42 within patient 40. In the illustrated embodiment, a lumen 36 of needle 30 is depicted. Lumen 36 is adapted to run the entire length of needle 30 such that it runs from needle tip 33, through the length of needle cannula 32 and to the proximal end of hub 34.

**[0032]** As will be appreciated by those skilled in the art, a variety of types and configurations of access apparatus can be utilized without departing from the scope and spirit of the present invention. For example, in one embodiment, catheter 22 comprises a stiffened material which does not need a needle apparatus to be advanced to the desired position within the patient's tissue. In another embodiment, the needle is first inserted into the patient's tissue and then a catheter is advanced subsequently to the desired location within the patient's tissue. According to another embodiment, the valved connector is connected directly to the access apparatus once it has already been positioned within the patient.

**[0033]** Figure 1D illustrates valved connector 10 once it has been positioned within the volume of fluid 42 within a patient 40. In the illustrated embodiment, needle tip 33 and catheter tip 28 have been advanced through the patient's skin 46, through the patient tissue 44, and into volume of fluid 42. In this manner, a direct fluid path is provided through access apparatus 20 and into valved connector 10.

**[0034]** In the illustrated embodiment, needle 30 provides a direct fluid path through the middle of the valve provided in connection with valved connector 10. As a result, when needle tip 33 and catheter tip 28 are positioned within the volume of fluid, fluid 48 from the volume of fluid 42 pass along the length of catheter 22,

through access apparatus hub 24, along the length of valved connector 10, and out through the proximal end of lumen 36 of needle apparatus 30.

**[0035]** Figure 1E illustrates valved connector 10 after needle apparatus 30 has been removed from valved connector 10 and access apparatus 20. When needle apparatus 30 has been removed from valved connector 10, catheter tip 28 remains positioned within the volume of fluid 42 within the patient 40. The valve associated with valved connector 10 prevents the passage of fluid out the proximal end of main lumen 18. As a result, while access apparatus 20 remains in a desired position such that the catheter tip 28 is positioned in the volume of fluid, undesired leakage of the fluid from access apparatus and valved connector 10 is limited. In this manner, other aspects of a procedure can be performed without the ongoing loss of fluid.

**[0036]** In one embodiment, a guide wire can be threaded through valved connector 10, access apparatus 20, and into the volume of fluid. A secondary apparatus can be advanced to a desired position within the patient at a subsequent portion of the procedure. For example, the valved connector and access apparatus may be removed once the volume of fluid has been drained. Subsequently, a catheter or interventional apparatus could be advanced to the location of the volume of fluid. According to another embodiment, access apparatus 20 is positioned within the patient's vasculature, and valved connector 10 prevents or minimizes the leakage of blood or fluid from the patient's vasculature. In this embodiment, a guide wire or other instrument can be advanced through valved connector while hemostasis is maintained.

**[0037]** Figure 1F is a perspective view of valved connector 10 and access apparatus 20 in which catheter tip 28 is positioned within a volume of fluid and a drainage apparatus 50 is connected to the proximal end of valved connector 10. In the illustrated embodiment, catheter tip 28 remains positioned within the volume of fluid 42 positioned within patient 40. A drainage apparatus 50 is connected to the proximal end of valved connector 10. Drainage apparatus 50 includes a luer connector 52 which is threadably coupled to the male connector 16 (see Figure 1E) positioned on the proximal end of valved connector 10. When luer coupler is connected to the distal end of valved connector 10, the valve positioned within valved connector 10 is automatically opened and fluid is allowed to pass through valved connector and into drainage apparatus 50. In the illustrated embodiment,

tubing 54 is connected to luer connector 52. Tubing 54 passes the fluid which is issuing from valved connector 10 to a secondary location. In the illustrated embodiment, tubing 54 is depicted as terminating to show the manner in which fluid can pass through and from tubing 54. In one embodiment, tubing 54 may be positioned over a tray or receptacle for receiving the bodily fluid. In another embodiment, tubing 54 may be connected to a bag or other receptacle for containing the fluid as it is drained or flows from the patient. In yet another embodiment, tubing 54 may be connected to a hemostasis valve or other apparatus to provide desired functionality, depending upon the requirements of the procedure being performed.

**[0038]** As will be appreciated by those skilled in the art, a variety of types of mechanisms can be utilized without departing from the scope and spirit of the present invention. For example, in one embodiment, a connector that is not threaded is secured to the distal end of the valved connector. In another embodiment, both the proximal and distal ends of the valved connector have the same type of securement configuration. For example, in one embodiment, both ends have a female connector. In another embodiment, both ends have a male connector. In another embodiment, both ends are adapted to include a compression or other fitting which does not require threads. In yet another embodiment, other known connection or securement type configurations can be utilized without departing from the scope and spirit of the present invention.

**[0039]** Figure 2 is a perspective view of the valved connector according to one embodiment of the present invention. In the illustrated embodiment, valved connector 10 includes a distal body component 60, and a proximal body component 62. Additionally, valved connector 10 includes a seal 64, a seal engagement apparatus 66, and a spring 68. Distal body component 60 is associated with female connector 14. Proximal body component 62 is associated with male connector 16 and the proximal end of valved connector 10. In the illustrated embodiment, distal body component 60 includes a seal engagement apparatus receiving channel 70. In one embodiment, seal engagement apparatus receiving channel 70 has a slight frusto-conical design which permits axial movement of seal engagement apparatus 66. Distal body component 60 also includes a seal chamber 72. Seal chamber 72 is adapted to receive seal 64. Additionally, a spring 68 is adapted to be positioned between seal 64 and distal body component 60. Spring 68 facilitates the desired

engagement of seal 64 with seal chamber 72. In the illustrated embodiment, seal chamber 72 includes a sealing channel 74. Sealing channel 74 receives a proximal sealing flange 76 of seal 64. In this manner, the pressure applied by spring 68 on seal 64 causes the desired engagement between proximal sealing flange 76 and sealing channel 74. In this manner, when seal engagement apparatus 66 is not engaged by a secondary mechanism, spring 68 can maintain desired sealing between seal 64 and seal chamber 72. When seal engagement apparatus is positioned within channel 70 and seal 64 is positioned within seal chamber 72, spring 68 is positioned between seal 64 and distal body component 60. Distal body component 60 includes a spring engagement post 80. Spring engagement post is sized such that the outer diameter of the spring engagement post 80 can be positioned within the inner diameter of spring 68. In this manner, the desired alignment of spring 68 relative to spring engagement post 80 is maintained. Once seal engagement apparatus 66, seal 64, and spring 68 have been positioned relative to distal body component 60 and proximal body component 62, distal body component 60 can be secured relative to proximal body component 62. Distal body component 60 includes an engagement void 82. Proximal body component 62 includes an engagement member 84. When distal body component 60 and proximal body component 62 are secured together, engagement member 84 is positioned within engagement void 82 facilitating desired coupling of distal body component 60 to proximal body component 62. In this manner, the internal components of valved connector including seal 64, seal engagement apparatus 66, and spring 68 are positioned in their desired location to facilitate desired operability of the components of valved connector 10.

**[0040]** In the illustrated embodiment, seal 64 includes a distal sealing flange 78. Distal sealing flange 78 facilitates the desired positioning of spring 68 relative to seal 64. In this manner, when seal 64 is displaced laterally by the engagement of seal engagement apparatus 66, a uniform and desired amount of compression is provided by spring 68 to return seal 64 to its desired position within seal chamber 72 when such axial forces are no longer exerted by seal engagement apparatus on seal 64.

**[0041]** As will be appreciated by those skilled in the art, a variety of types and configurations of valved connector components can be provided without departing

from the scope and spirit of the present invention. For example, in one embodiment, the body of valved connector is provided as a single component, rather than as first and second components. In another embodiment, the valve body is provided in a clam shell fitting, rather than as proximal and distal ends. In yet another embodiment, the body of valved connector is adapted such that the internal components can be inserted within or through the proximal or distal ends of the valved connector body. A retainment flange or other secondary apparatus is positioned to secure the components in their desired position.

**[0042]** Figure 3A and 3B are cross-sectional view of valved connector 10 according to one embodiment of the present invention. In the illustrated embodiment, the positioning of the internal components of valved connector 10 can be seen. In the illustrated embodiment, seal 64 is positioned between the proximal and distal ends of valved connector 10. Seal engagement apparatus 66 is positioned between the proximal end of valved connector 10 and the seal 64. Spring 68 is positioned between the distal end of the valved connector 10 and the seal 64. In other words, the seal engagement apparatus 66 is positioned between the end of the valved connector 10 into which a drainage apparatus is inserted and the seal 64. Spring 68 is positioned on the portion of the valved connector 10 opposite the end into which a drainage apparatus is inserted such that the valve 64 is positioned between the spring and the end of the valved connector 10 into which a drainage apparatus is inserted.

**[0043]** Seal engagement apparatus 66 is positioned within seal engagement apparatus receiving channel 70. Channel 70 includes a flange at its proximal most position, which prevents further axial movement of seal engagement apparatus 66 in a proximal direction. In the illustrated embodiment, the distal end of seal engagement apparatus 66 is positioned adjacent seal 64. Seal 64 is positioned within seal chamber 72. Seal 64 is positioned such that the outer periphery of seal 64 is positioned proximal to the proximal sealing flange 76 and is in abutment with a contact surface at the distal most extremity of seal engagement apparatus receiving channel 70. Additionally, proximal sealing flange 76 is positioned within sealing channel 74.

**[0044]** Spring 68 is positioned between seal 64 and distal body component 60. In particular, the proximal portion of spring 68 is positioned such that the outside

diameter of spring 68 is retained within distal sealing flange 78. The distal portion of spring 68 is positioned around spring engagement post 80 effectively retaining the angular orientation of spring 68 relative to seal 64. Spring 68 is sized such that a predetermined amount of tension is exerted against seal 64 retaining the desired engagement between seal 64 and the internal topography of seal chamber 72. In this manner, when a fluid column is positioned within the distal portion of main lumen 18, seal 64 prevents passage of the fluid from the distal portion of main lumen 18 to the proximal portion of main lumen 18.

**[0045]** Figure 3B illustrates a perspective cross-sectional view of valved connector 10 illustrating the juxtaposition of seal engagement apparatus 66, seal 64, spring 68, distal body component 60, and proximal body component 62.

**[0046]** In the illustrated embodiment, in the event that a column of fluid is positioned within the distal portion of main lumen 18, the axial movement of seal 64 disrupts the sealing engagement between seal 64 and the internal profile of proximal body component 62. In this manner, when drainage apparatus 50 is secured to valved connector 10, fluid can pass around the other periphery of seal 64 even though no component of drainage apparatus 50 is directly in contact with seal 64. In other words, a secondary component, in this case, seal engagement apparatus, passes the axial force provided by drainage apparatus. Opening the seal 64 and permitting the passage of fluids from the distal portion of valved connector 10 to the proximal portion of valved connector 10 and into drainage apparatus 50. As will be appreciated by those skilled in the art, a variety of types and configurations of drainage apparatus 50, which exert indirect forces on seal, can be utilized without departing from the scope and spirit of the present invention. For example, in one embodiment, the drainage apparatus connected to valved connector has a threaded coupling with valved connector. In another embodiment, a non-threaded fitting is provided. In another embodiment, a user can selectively apply or remove forces relative to the seal engagement apparatus to open and close the seal, even without requiring movement or separation and reconnection of the drainage apparatus. In yet another embodiment, the axial forces exerted on seal are provided directly from the drainage apparatus rather than utilizing an intermediary seal engagement apparatus.

**[0047]** Figure 4 is a cross-sectional view of valved connector 10. In the illustrated embodiment, a drainage apparatus 20 is provided in connection with the distal end of valved connector 10. Male connector 16 is secured to a female connecting portion of luer connector 52. Additionally, a post 90 has been positioned within the proximal portion of main lumen 18. In the illustrated embodiment, the distal portion of post 90 has been advanced such that it engages the tapered surface 67 of seal engagement apparatus 66.

**[0048]** In the illustrated embodiment, seal engagement apparatus 66 has a tapered surface 67. Tapered surface 67 provides a frusto-conical engagement surface which can engage a post of a secondary apparatus which is threaded through the proximal portion of main lumen 18. If the apparatus which is threaded through the proximal portion of main lumen 18 has a sufficient outside diameter, the distal portion of such apparatus will engage the wall of tapered surface 67 and provide a desired amount of axial force on tapered surface 67. In this manner, once a desired threshold force is provided, axial displacement of seal engagement apparatus is effectuated. In this manner, the forces exerted on tapered surface 67 are sufficient to overcome the tensile forces provided by spring 68 resulting in axial or lateral movement of seal 64. In this manner, desired sealing between seal 64 and seal chamber 72 are broken and fluids can pass around the outer periphery of seal 64. Passage of fluids around the outer periphery of seal 64 permits the passage of fluid from the distal portion of main lumen 18 to the proximal portion of main lumen 18.

**[0049]** Figure 5 is a cross-sectional view of valved connector 10 illustrating the manner in which a needle 30 can be utilized to permit the passage of fluid through seal 64. In the illustrated embodiment, a needle cannula has been advanced through main lumen 18 of valved connector 10 such that a needle cannula 32 is positioned through the middle of seal 64. Lumen 36 is positioned through the middle of needle 30 allowing the passage of fluid from the distal end of valved connector 10 to the proximal end of valved connector 10, thereby facilitating the passage of fluids through valved connector 10.

**[0050]** According to one embodiment of the present invention, the seal of valved connector includes crisscross bicuspid-type slits, which permit the passage of a needle, cannula, or a guide wire through the middle of valved connector. In another

embodiment, the material properties permit the passage of a needle through valve, while providing desired resealing upon the removal of the needle through valve. In yet another embodiment, a combination of the material properties and slit configuration can be utilized without departing from the scope and spirit of the present invention. As can be seen, the configuration of seal engagement apparatus 66 is configured such that the frusto-conical sloping of tapered surface 67 permits the passage of smaller instruments, such as a needle, or guide wire, through the middle of main lumen without obstruction and without resulting in lateral displacement of seal engagement apparatus 66. In this manner, both a smaller diameter apparatus, such as needle 30 or a guide wire, can be passed through seal 64, or alternatively, a larger connector, such as that with drainage apparatus 50 shown in Figure 4, can be utilized to permit the passage of fluids through valved connector 10.

**[0051]** Figure 6A is a perspective view of a valved apparatus in which a catheter, needle, or trocar is integrally coupled to a valved connector. In other words, the hub of the access apparatus includes internal components which allow the use of a drainage apparatus connector or a needle or other apparatus to open the seal associated with the hub. In the illustrated embodiment, an integral component is provided. Integral component includes a proximal end 102 and a distal end 104. In the illustrated embodiment, proximal end 102 comprises a threaded coupler and the distal end includes a catheter apparatus 104. A hub 106 is positioned between proximal end 102 and distal end 104. Hub 106 includes internal components which are similar in operation and function to valved connector 10 of Figures 1A through 5. In the illustrated embodiment, the internal components of hub 106 comprise a seal engagement apparatus 108, a seal 110, and a spring 112. When an engagement apparatus is positioned in cooperative communication with the proximal end 102 of integral component 100, seal engagement apparatus 108 is moved in an axial direction which overcomes the forces of spring 112. In this manner, seal 110 can be moved distally, permitting the passage of fluids through a main lumen 114 of integral component 100. Alternatively, a needle, trocar, guide wire, or other device can be advanced through the middle of seal 110.

**[0052]** Figure 6B illustrates the insertion of a needle apparatus. Needle apparatus can provide sufficient rigidity to the distal end of integral component to

allow insertion of the distal end of integral component into a desired position within a patient. In the illustrated embodiment, the needle of the needle apparatus is positioned through the middle of seal 110. Additionally, a component of the hub of the needle apparatus engages the seal engagement apparatus 108, causing movement of the seal 110 while also allowing the passage of fluids around the external portion of seal 110.

**[0053]** Figure 7A is a side view of a valved connector 100 according to one embodiment of the present invention. In the illustrated embodiment, valved connector 100 is adapted to be utilized with a catheter or other instrument which is positioned within an access site and which is connected to a volume of bodily fluid within a patient. The volume of bodily fluid can be a volume of fluid that is to be drained from the patient. Alternatively, the volume of fluid can be a volume of urine within the patient's bladder or other urinary tract location, blood from the patient's vasculature, or any other area where fluid is positioned within the patient. In some embodiments, the volume of fluid is not desired to be drained but rather retained within the patient and the valve apparatus is adapted to allow desired instruments or other procedures to be performed in a largely bloodless and hemostatic manner.

**[0054]** In the illustrated embodiment, valved connector 100 comprises a distal body component 110 and a proximal body component 112. Proximal body component 112 includes threads 114 and collar 116. Distal body component 110 includes taper 120 at distal tip 118, threads 122 and extension section 124. In the embodiment, proximal body component 110 is connected to a catheter, or other access device inserted into the patient. Threads 114 comprise a luer connector 114 which can be utilized to secure additional medical devices or components to valved connector 100.

**[0055]** Collar 116 is positioned as a rim or stop against which threaded components abut to control advancement of threaded coupling components beyond their intended threaded advancement. Threads 122 have a smaller thread displacement than threads 114. Threads 122 can provide a long term secure coupling to the apparatus to which valved connector 100 is secured. Taper 120 of distal tip 118 provides a mechanism to provide simple and efficient insertion of distal tip 118 into a female coupling member during securement of valved connector 100 to tubing, a connector or another medical apparatus. Extension section 124 is

positioned between collar 116 and threads 122. Extension section 124 provides displacement to ensure desired coupling of valved connector 100 to a secondary apparatus. According to one aspect of the present invention, extension section 124 can allow a desired length of distal body component 110 while minimizing the total length of threads 122.

**[0056]** As will be appreciated by those skilled in the art, a variety of types and configurations of valved connectors can be provided without departing from the scope and spirit of the present invention. For example, in one embodiment, the threads on the proximal body component have the same displacement as the threads on the distal body component. In another embodiment, one or both of the threads are provided in a female configuration rather than a male configuration.

**[0057]** Figure 7B illustrates a cross-sectional side view of valved connector 100 according to one embodiment of the present invention. In the illustrated embodiment, valve 126 is secured relative to the other components of valved connector 100 by a securement flange 132 of a cap member 130. Valve member 126 includes a securement flange 128 on its outside diameter. Securement flange 128 is secured cap member flange 132 and valve securement portion 134. Cap member 130 slides over valve securement portion 134 such that valve securement portion 134 comprises a male member which fits inside and contacts the inside diameter of valve securement portion 134. Distal portion 136 of cap member 130 contacts a proximal portion 138 of collar 116. In this manner, desired securement of cap member 130 relative to proximal body component is provided while also securing valve 126 .

**[0058]** A main lumen 140 is positioned along the length of valved connector 100. Main lumen 140 includes a valve chamber 142, a tapered portion 144 and a distal lumen portion 146. Valve 126 is configured to allow a medical instrument, needle or dilator to pass from the external environment into main lumen 140 while maintaining hemostasis within main lumen 140. In the event that the apparatus which opens valve 126 comprises a dilator which is intended to provide open and ongoing flow from main lumen 140, through the dilator and into a secondary medical instrument, such dilators can be secured in threaded relationship to threads 114. The size and shape of such dilators can be received within the enlarged valve chamber 140 without obstruction or damage to valved connector 100. In the event a needle,

guidewire or other instrument is provided to pass along the entire length of main lumen 140, the instrument can pass through valve chamber 142 and then be directed into the smaller diameter of distal lumen portion 146 by tapered portion 144.

**[0059]** One of the benefits of utilizing a valved connector 100 is that valved connector 100 is adapted to allow a needle, cannula, or other implement to be passed through main lumen 18. The configuration of the valved connector 100 allows not only the passage of the instrument, but also the passage of fluid through the needle permitting the passage of fluid from the distal end of valved connector 10 to the proximal end of valved connector 10. Additionally, in longer term applications, such as dialysis or drainage devices, valved connector 100 can be removed and replaced with a new valved connector to maintain and ensure a sterile environment, continued desired operability of the valved connector 100 or to replace a damaged or worn out valved connector 100.

**[0060]** As will be appreciated by those skilled in the art, a variety of types and configurations of valved connectors can be utilized within the scope and spirit of the present invention without departing from the scope and spirit of the present invention. For example, in one embodiment, the valved connector can be configured for use in connection with one or more of drainage catheter, an IV catheter, a dialysis catheter, an IV set, an IV introducer needle or other illustrative medical apparatus and applications.

**[0061]** The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

## CLAIMS

What is claimed is:

1. A valved connector configured to be placed in fluid communication with a volume of bodily fluid within a patient, the valved connector adapted to selectively permit the passage of fluid from the volume of fluid within the patient to a location external to the patient, the valved connector adapted to be coupled to a catheter, needle or other device which is placed in fluid communication with the volume of fluid within the patient's body; the valved connector comprising:

a body;

a distal end adapted to be placed in fluid communication with a volume of bodily fluid within a patient or to be coupled to a secondary apparatus which is placed in fluid communication with a volume of bodily fluid within a patient;

a proximal end positioned on the side of the body opposite the distal end;

a main lumen allowing a patient's bodily fluid to pass from the distal end to the proximal end of the valved connector;

a valve positioned between the distal end and proximal end of the valved connector and in fluid communication with main lumen;

wherein the main lumen includes a valve chamber in connection with the proximal end and a distal lumen portion in connection with the distal end, and wherein a tapered lumen portion is positioned between the valve chamber and the distal lumen portion to facilitate the passage of needles, guidewires or other medical instruments from a larger diameter of the valve chamber to a smaller diameter of the distal lumen portion.

2. The valved connector of claim 1, wherein the tapered lumen portion tapers from a larger diameter corresponding with the inside diameter of the valve chamber and a smaller diameter corresponding with the inside diameter of the distal lumen portion.

3. The valved connector of claim 1, wherein the body comprises a proximal body component and a distal body component.

4. The valved connector of claim 3, wherein the valve chamber is positioned in one of the proximal body component and the distal body component.

5. The valved connector of claim 4, wherein the valve chamber is positioned in the proximal body component and the valve is openable in response to securing of a secondary component to the proximal body component.

6. The valved connector of claim 5, wherein the valve is openable in response to the introduction of a needle or other elongate instrument through the main lumen.

7. The valved connector of claim 6, wherein the valve automatically closes in response to removal of the needle or other elongate instrument or secondary component secured to the proximal body component.

8. The valved connector of claim 7, wherein the proximal body component and distal body component are securely coupled to one another to secure the components of the valve within the main lumen.

9. A valved connector configured to be placed in fluid communication with a volume of bodily fluid within a patient, the valved connector adapted to selectively permit the passage of fluid from the volume of fluid within the patient to a location external to the patient, the valved connector adapted to be coupled to a catheter, needle or other device which is placed in fluid communication with the volume of fluid within the patient's body; the valved connector comprising:

a body;

a distal body component having a male adapter configured to threadably engage with an apparatus which is in fluid communication with a volume of bodily fluid within a patient or to be coupled to a secondary apparatus which is placed in fluid communication with a volume of bodily fluid within a patient;

a proximal body component having a male adapter which can be threadably secured to a female threaded apparatus;

a main lumen allowing a patient's bodily fluid to pass from the distal body component of the to the proximal body component of the valved connector;

a valve positioned between the proximal body component and the distal body component and being in fluid communication with the main lumen;

wherein the main lumen includes a valve chamber in connection with the proximal end and a distal lumen portion in connection with the distal end.

10. The valved connector of claim 9, wherein the valve comprises a seal, a seal engagement apparatus and an automatic closing component.

11. The valved connector of claim 10, wherein automatic closing component comprises a spring.

12. The valved connector of claim 11, wherein the valve chamber includes a sealing channel for sealing the outer periphery of the seal when the valve is in a non-actuated position.

13. The valved connector of claim 12, wherein the seal is selectively separated from at least a portion of the sealing channel when the valve is in an actuated position.

14. The valved connector of claim 12, wherein the seal engagement apparatus can move the valve from a non-actuated position to an actuated position when engaged with the seal.

15. The valved connector of claim 14, wherein the seal engagement apparatus separates the seal from sealed engagement with the sealing channel when the seal engagement apparatus is actuated.

16. The valved connector of claim 15, wherein the seal engagement apparatus is actuated by threaded coupling of a leur connector to the proximal body component of the valved connector.

17. The valved connector of claim 16, wherein decoupling of the luer connector from the proximal end of the valved connector allows the spring to bias the seal into sealed engagement with the sealing channel.

18. A valved connector configured to be placed in fluid communication with a volume of bodily fluid within a patient, the valved connector adapted to selectively permit the passage of fluid from the volume of fluid within the patient to a location external to the patient, the valved connector adapted to be coupled to a catheter, needle or other device which is placed in fluid communication with the volume of fluid within the patient's body; the valved connector comprising:

a body;

a distal body component adapted to be placed in fluid communication with a volume of bodily fluid within a patient or to be coupled to a secondary apparatus which is placed in fluid communication with a volume of bodily fluid within a patient;

a proximal body component positioned on the opposite side of the body of the distal end;

a main lumen allowing a patient's bodily fluid to pass from the distal end of the to the proximal end of the valved connector;

a valve comprising a seal, the seal being positioned between the distal end and proximal end of the valved connector and in fluid communication with main lumen;

a seal engagement apparatus positioned in one of the distal body component and the proximal body component such that when a secondary member is secured to the proximal body component, the seal engagement apparatus is operably connected to the seal to open the seal and allow the passage of fluid through the main lumen between the distal body component and the proximal body component.

19. The valved connector of claim 19, wherein the main lumen includes a valve chamber in connection with the proximal body component and a distal lumen portion in connection with the distal body component.

20. The valved connector of claim 20, further comprising a tapered lumen portion positioned between the valve chamber and the distal lumen portion to facilitate the passage of needles, guidewires or other medical instruments from a

larger diameter of the valve chamber to a smaller diameter of the distal lumen portion.

21. The valved connector of claim 19, wherein the seal engagement apparatus is positioned within a seal engagement receiving channel of the proximal body component.

22. The valved connector of claim 22, wherein the seal is positioned within a seal chamber of the proximal body component.

23. The valved connector of claim 23, wherein the seal engagement apparatus is adapted to be urged in the direction of the seal when a secondary apparatus is threadably coupled to the proximal body component.

24. The valved connector of claim 24, wherein the seal engagement apparatus includes a tapered inner diameter.

25. The valved connector of claim 25, wherein the tapered inner diameter is adapted to receive a post of a threaded secondary member which is secured to the proximal body portion.

26. The valved connector of claim 26, wherein the threaded coupling of the secondary member and the proximal body component urges the seal engagement apparatus into engagement with the seal.

27. The valved connector of claim 27, wherein engagement between the seal engagement apparatus and the seal opens the seal and allows the flow of fluid through the main lumen from the distal body component to the proximal body component.

1 / 14

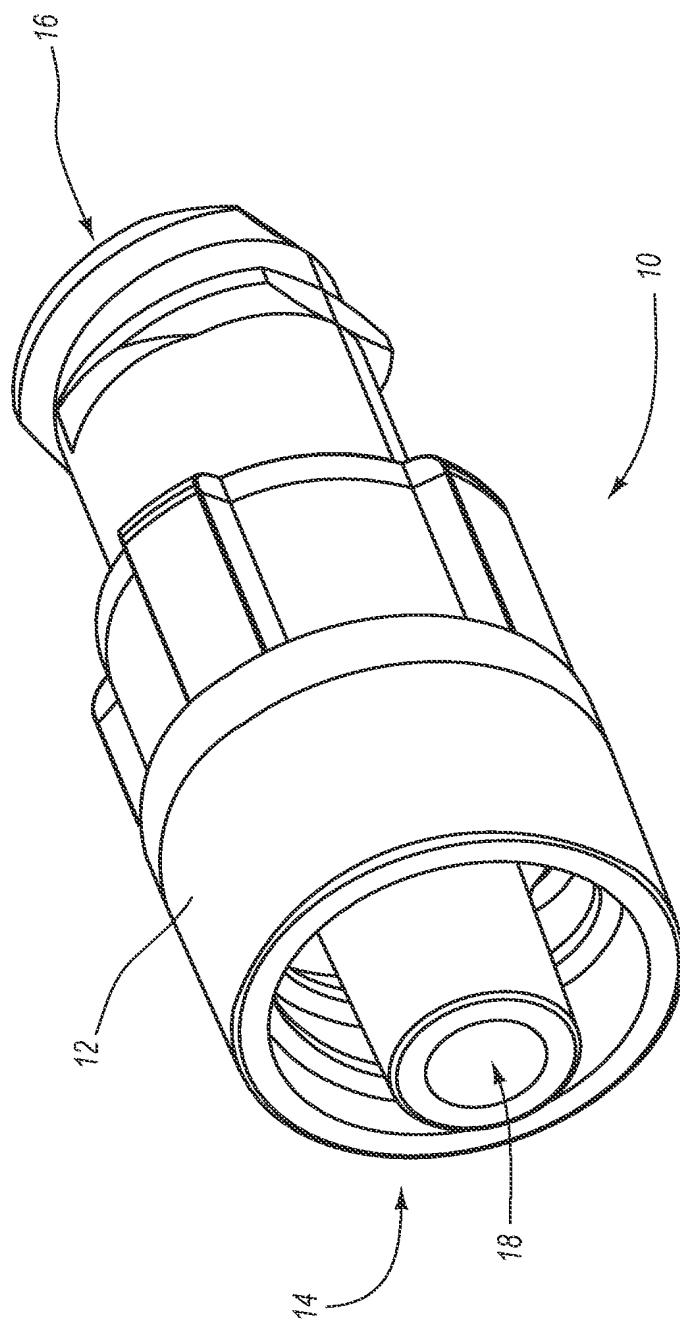


Figure 1A

2 / 14

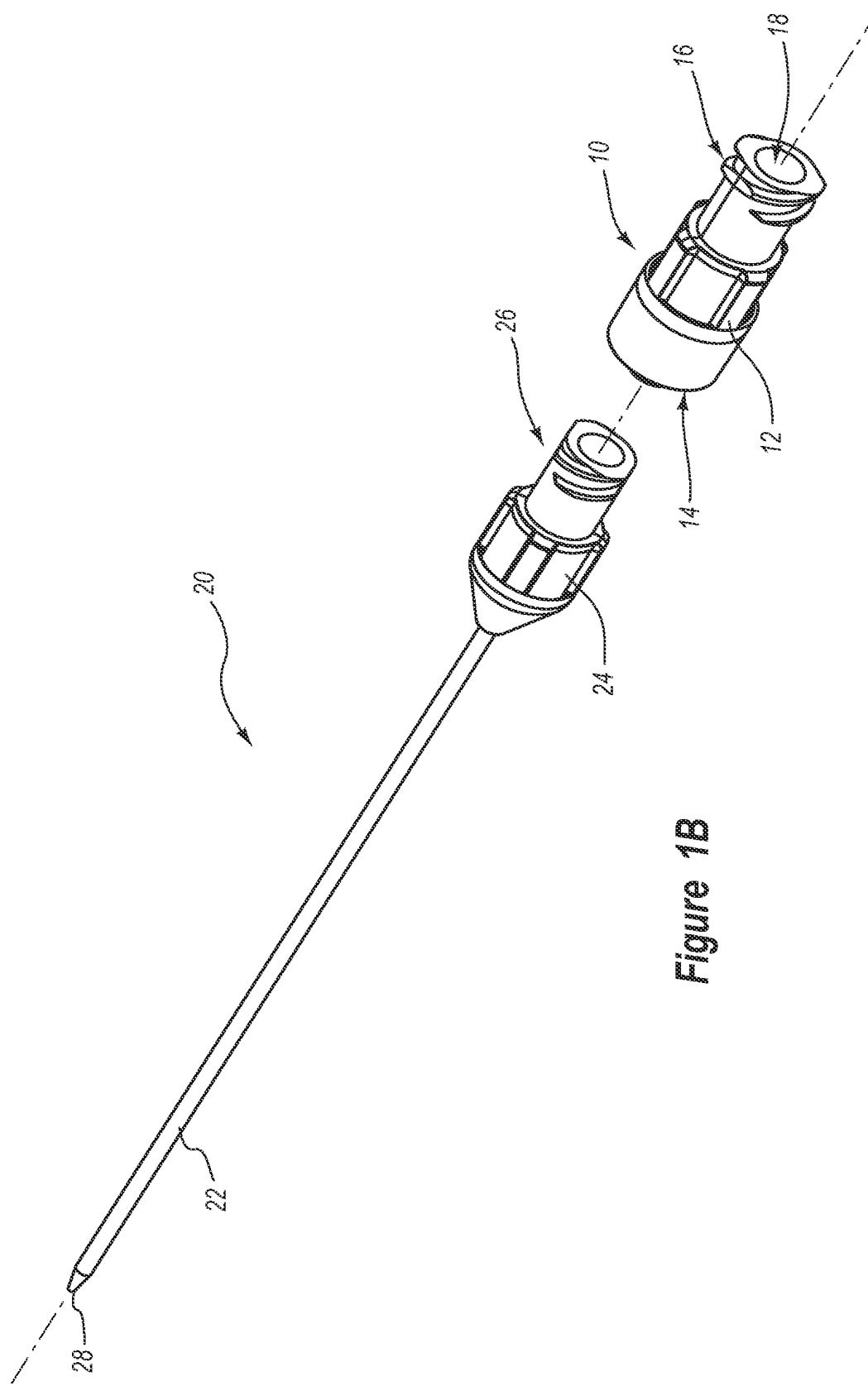
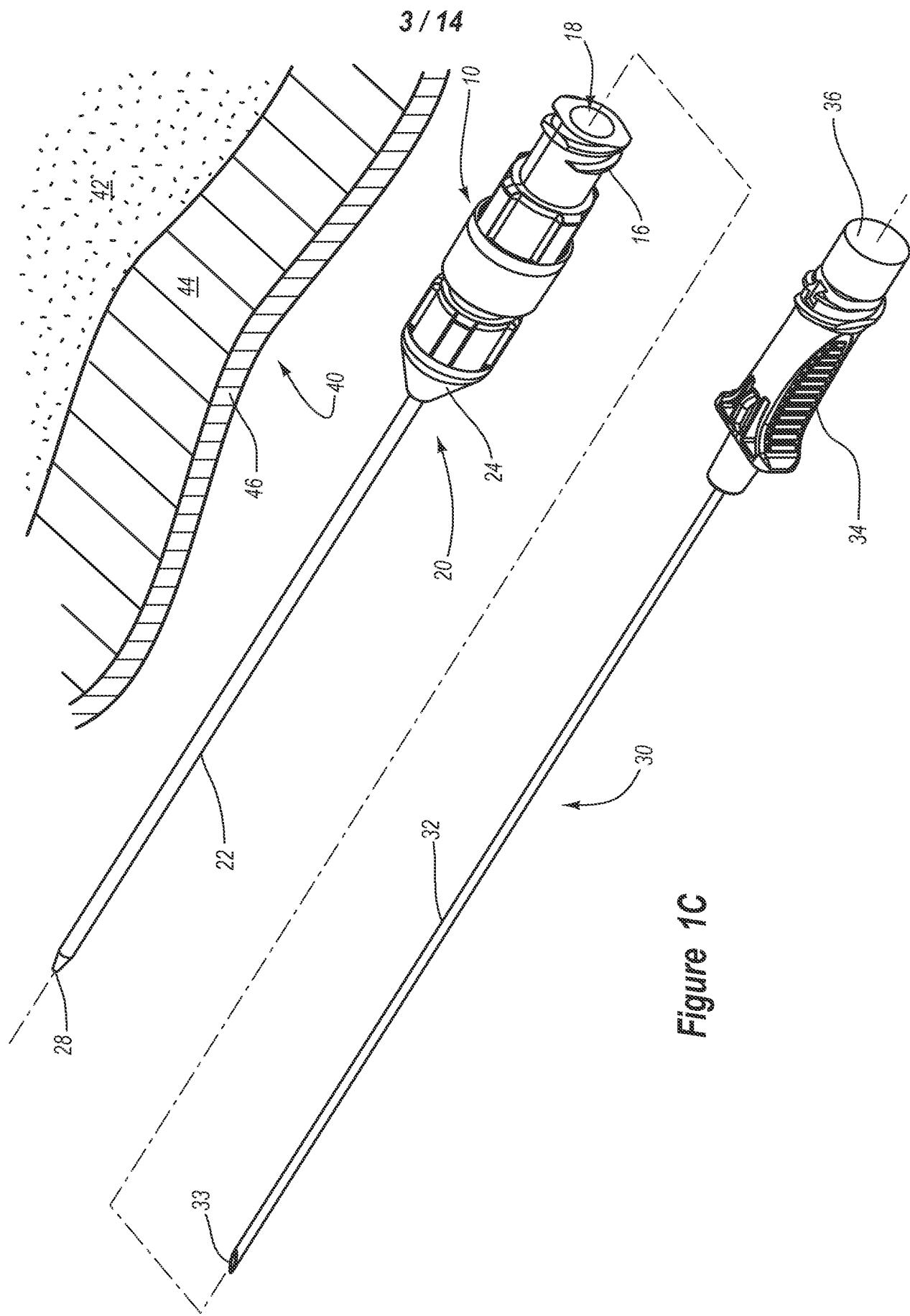


Figure 1B



4 / 14

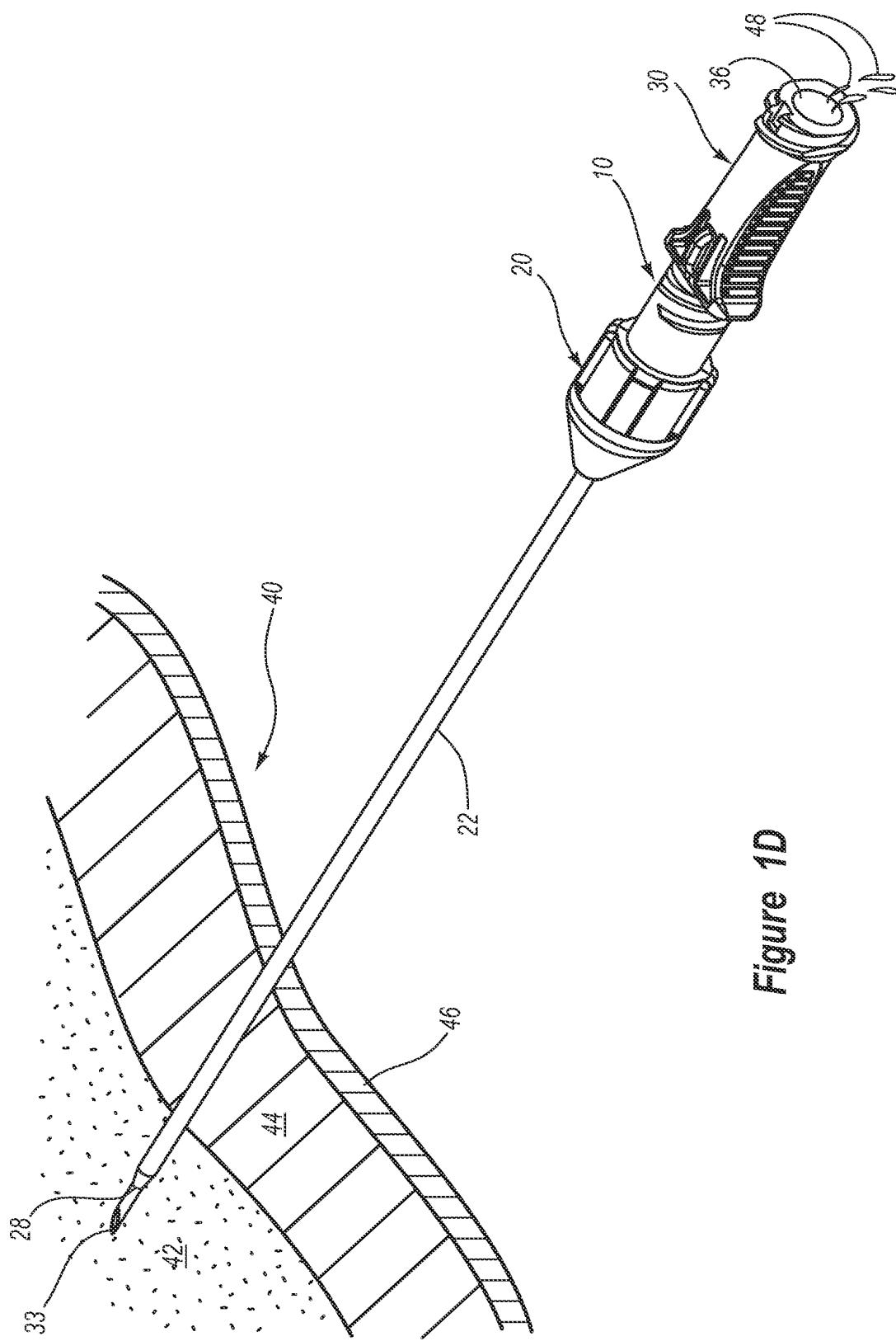


Figure 1D

5 / 14

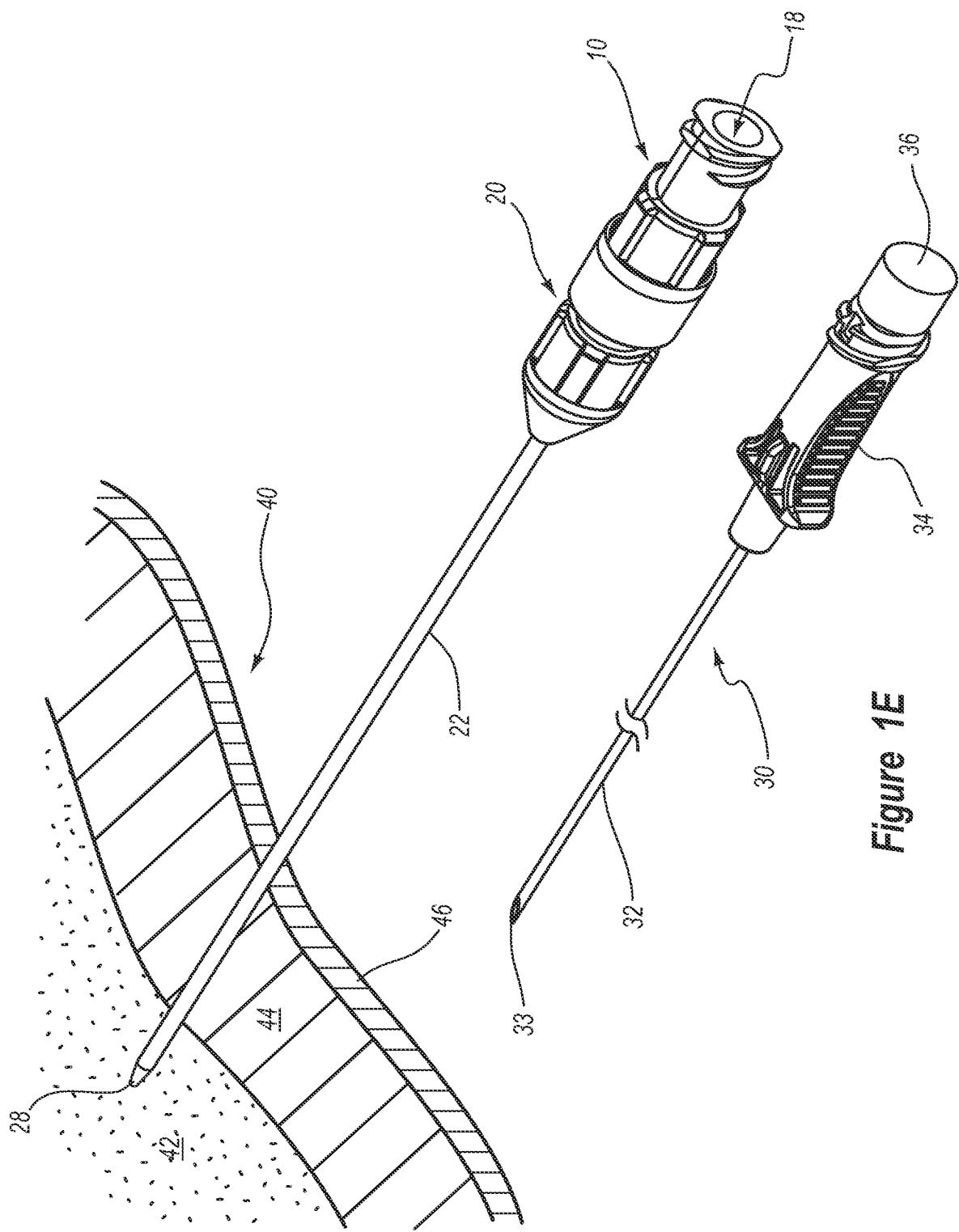
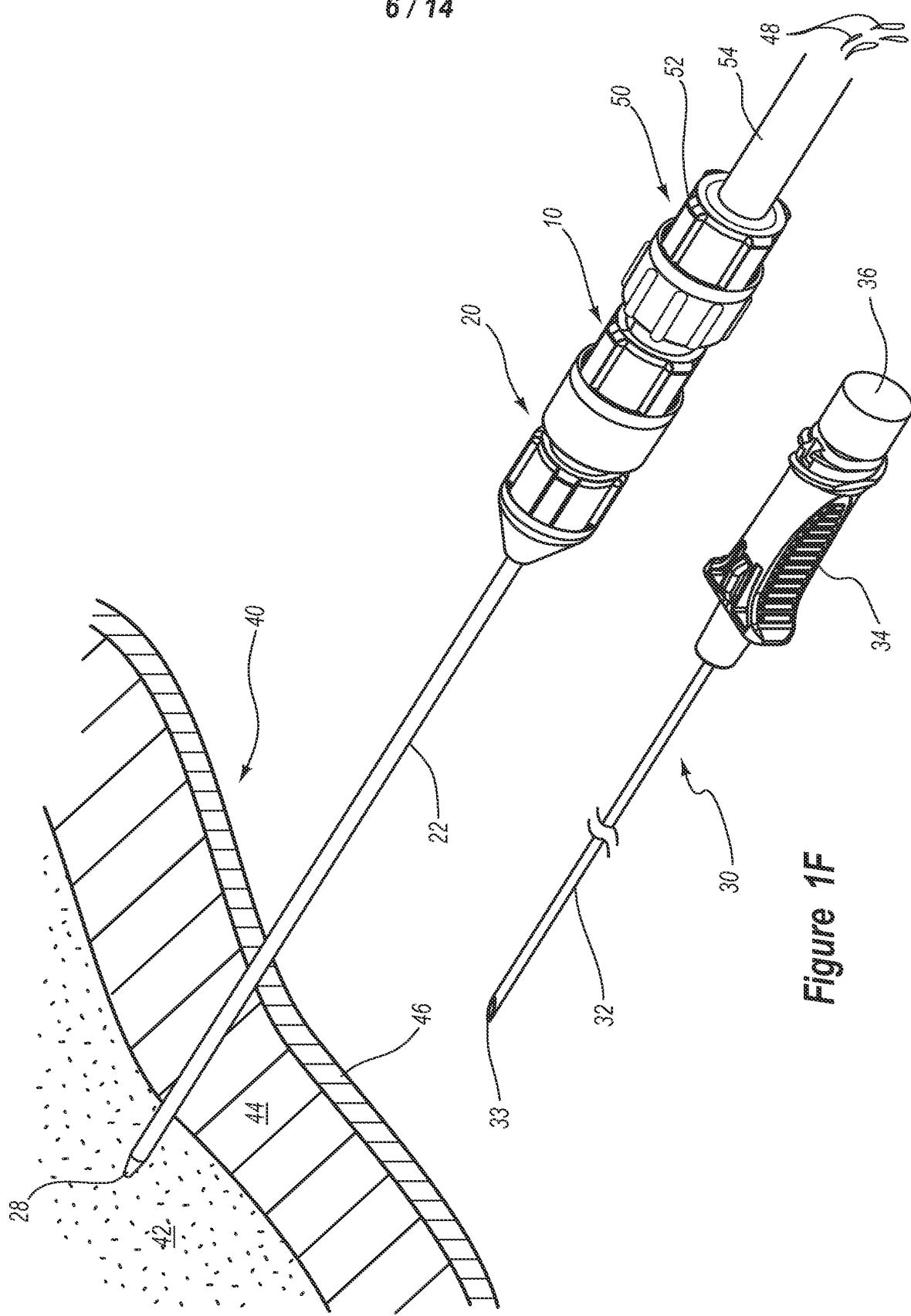


Figure 1E

6 / 14



## Figure 1E

7 / 14

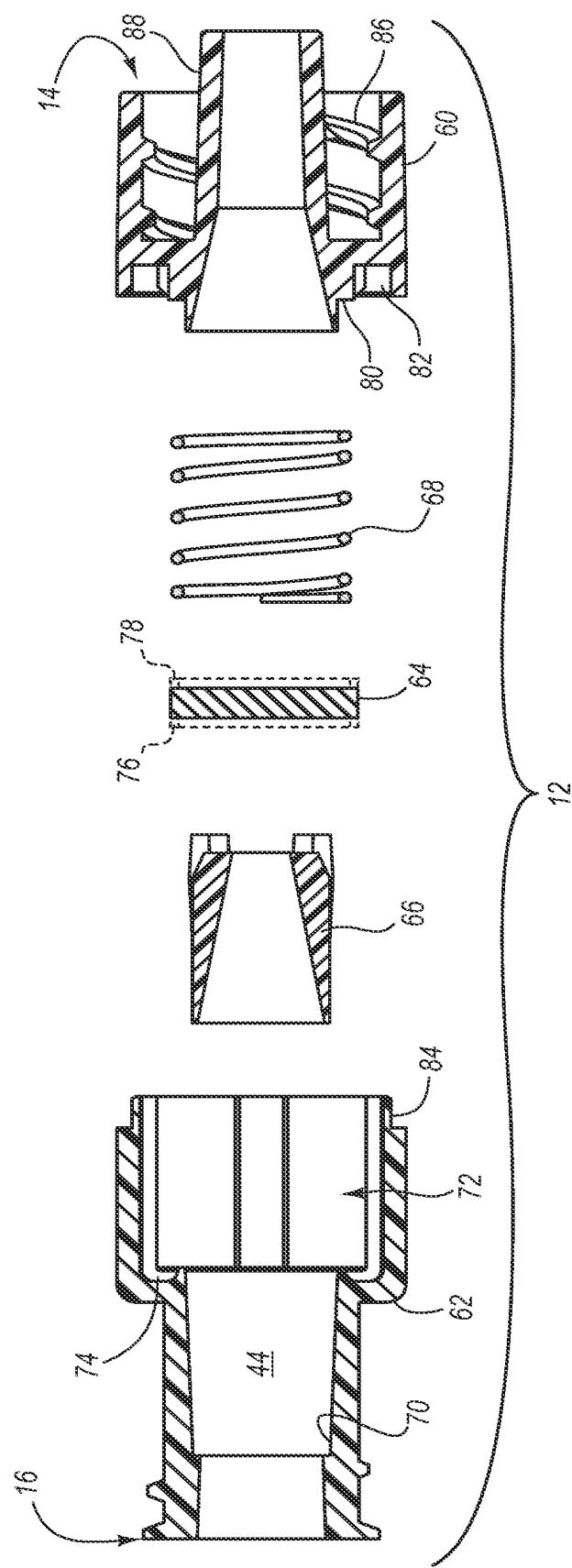


Figure 2

8 / 14

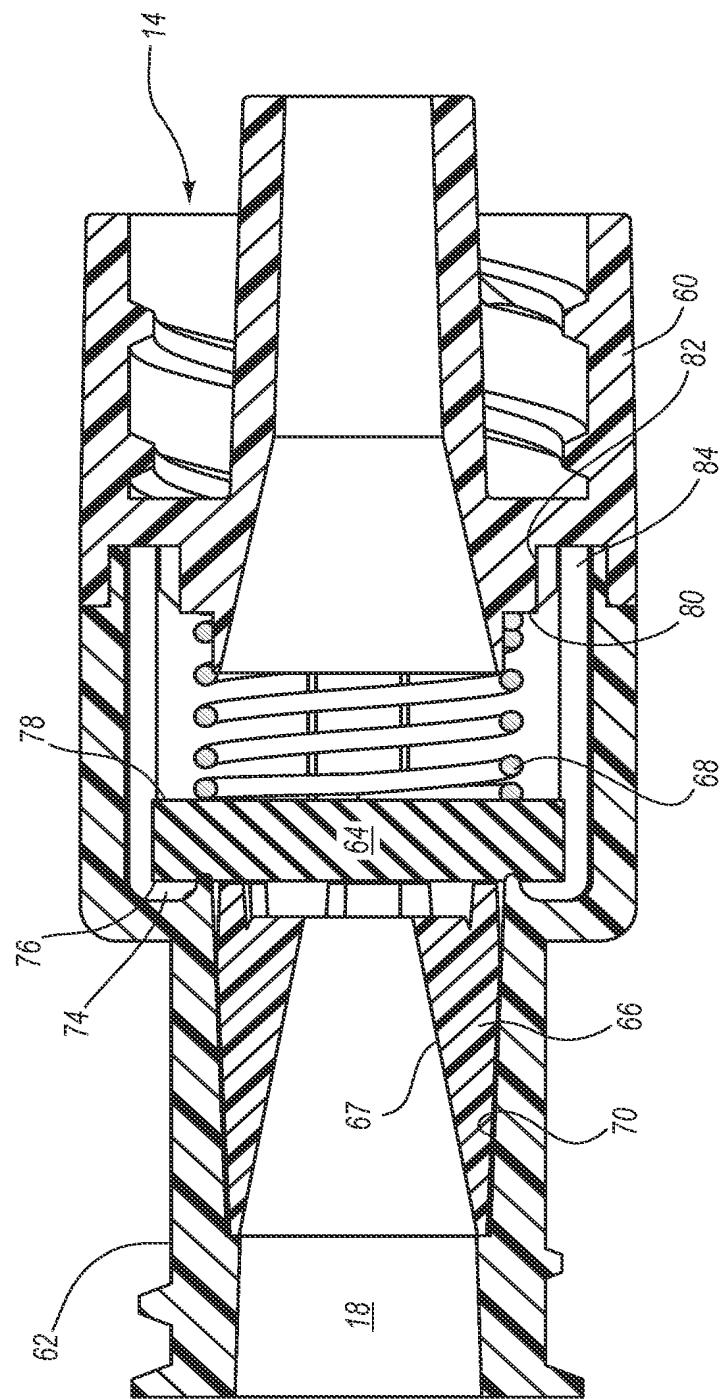
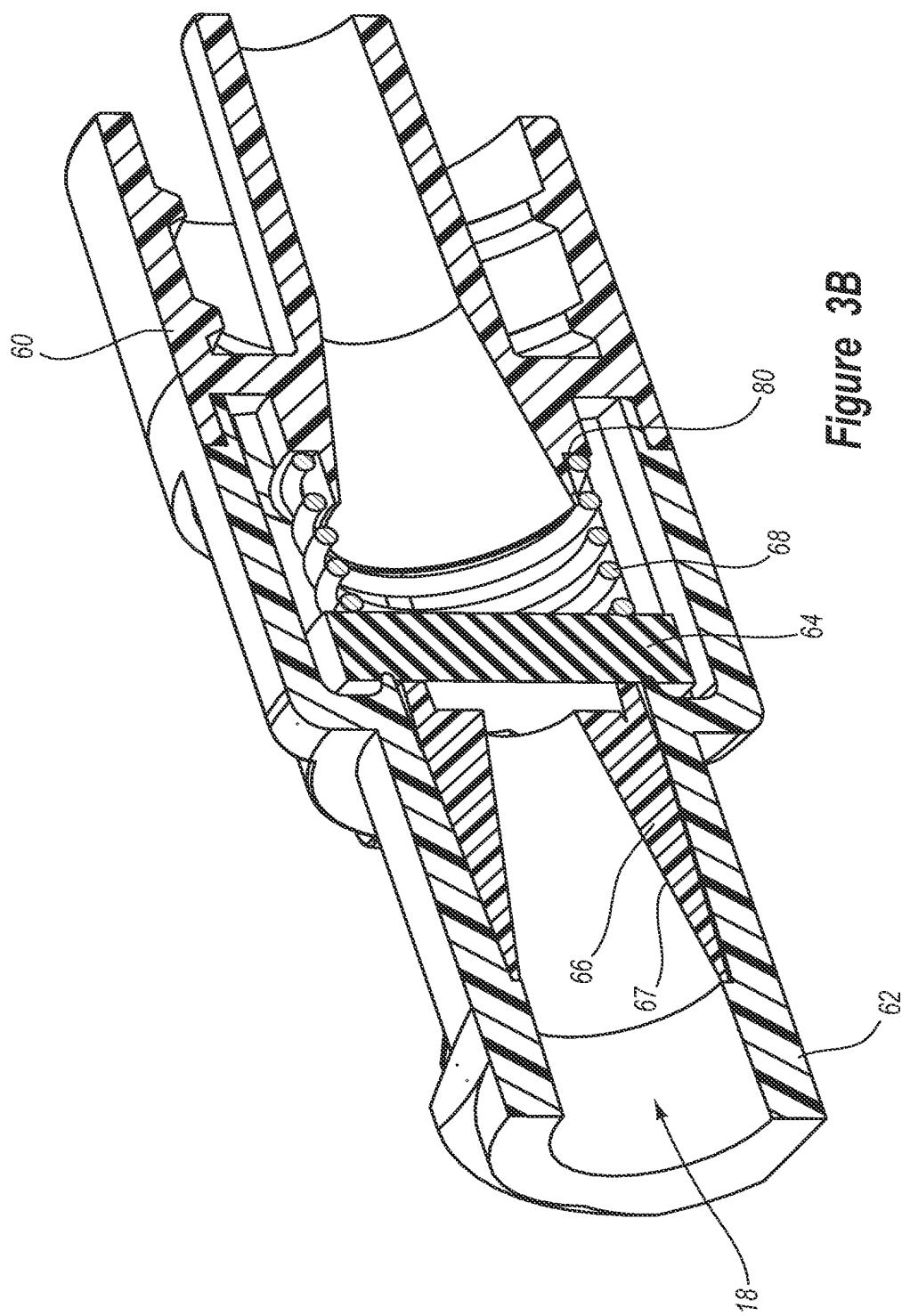


Figure 3A

9 / 14



10 / 14

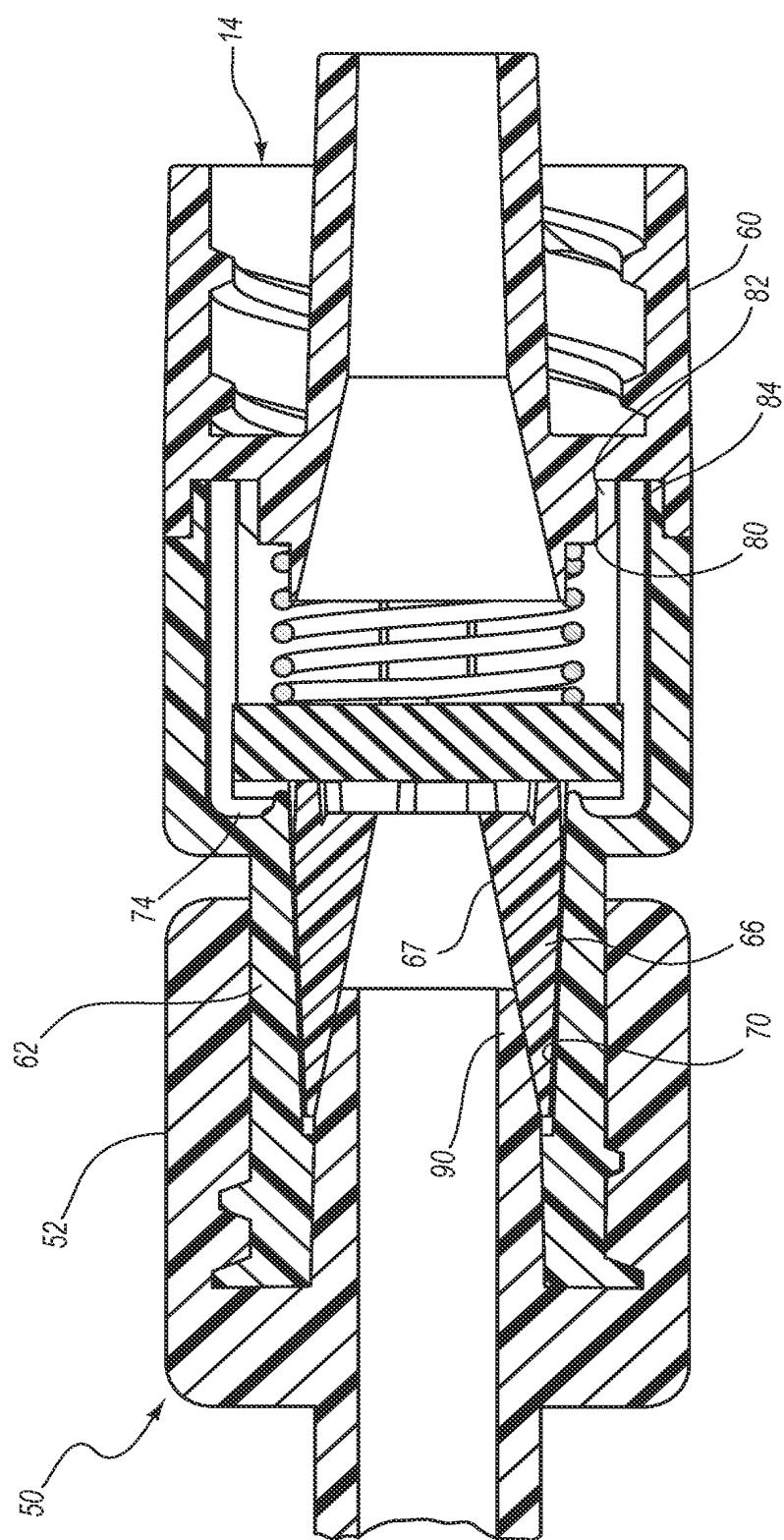


Figure 4

11 / 14

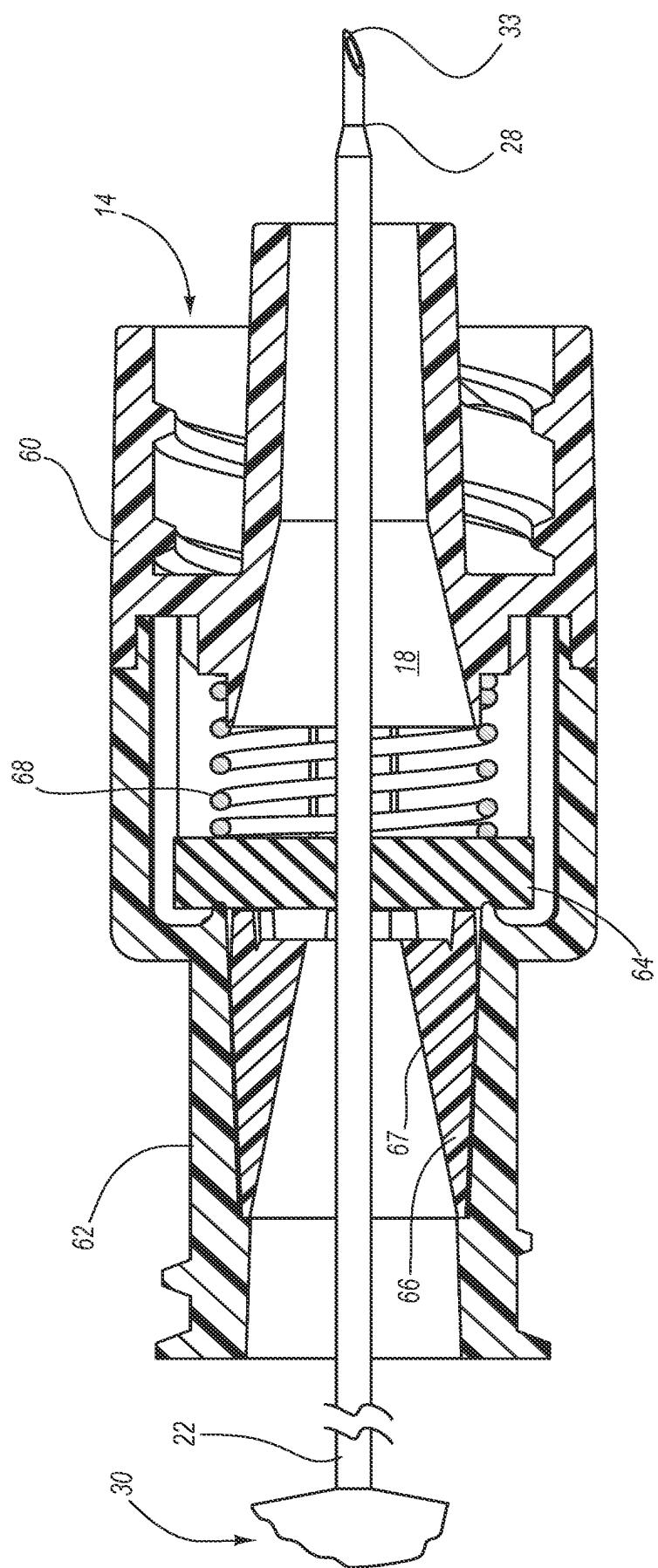


Figure 5

12 / 14

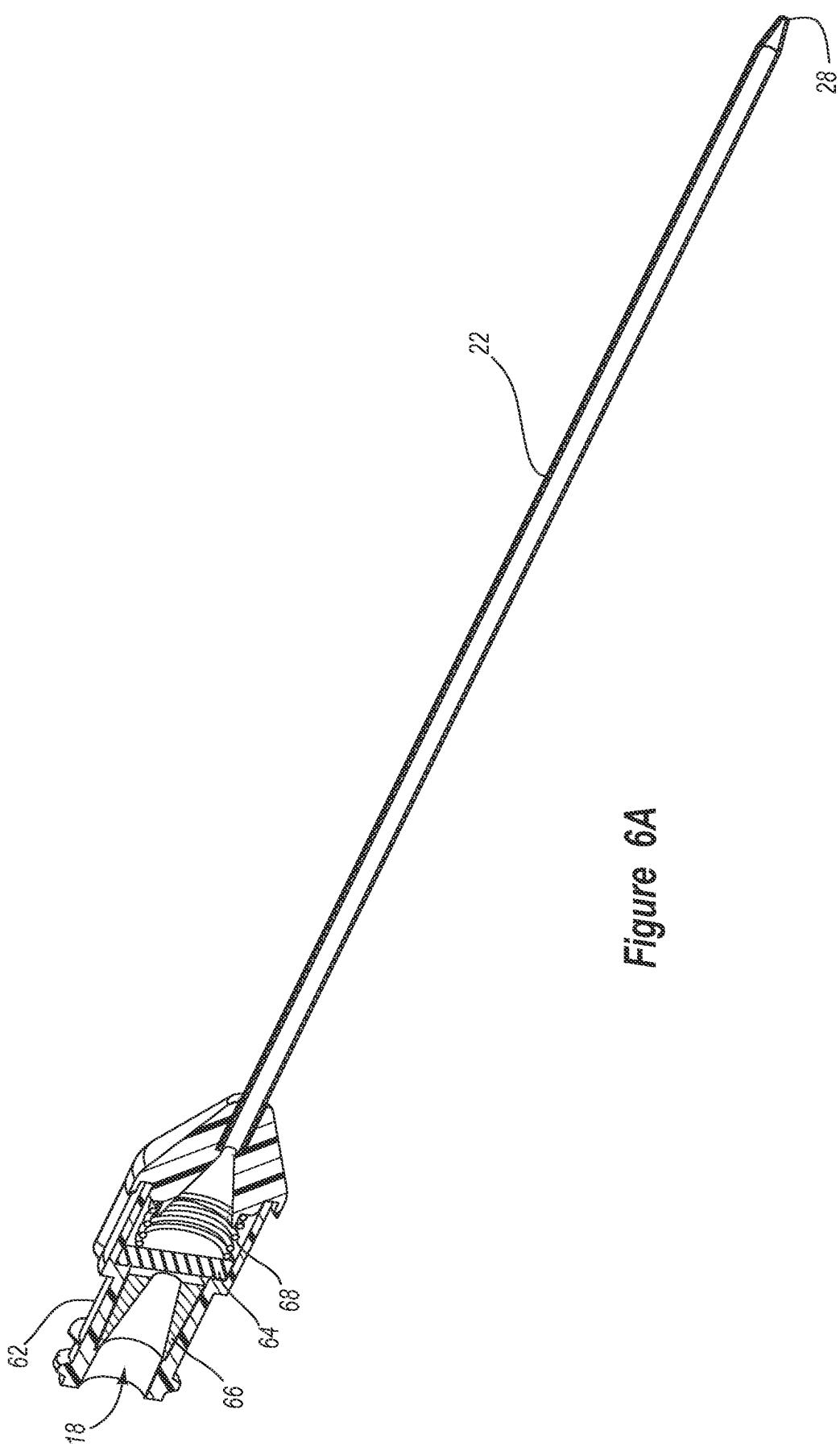


Figure 6A

13 / 14

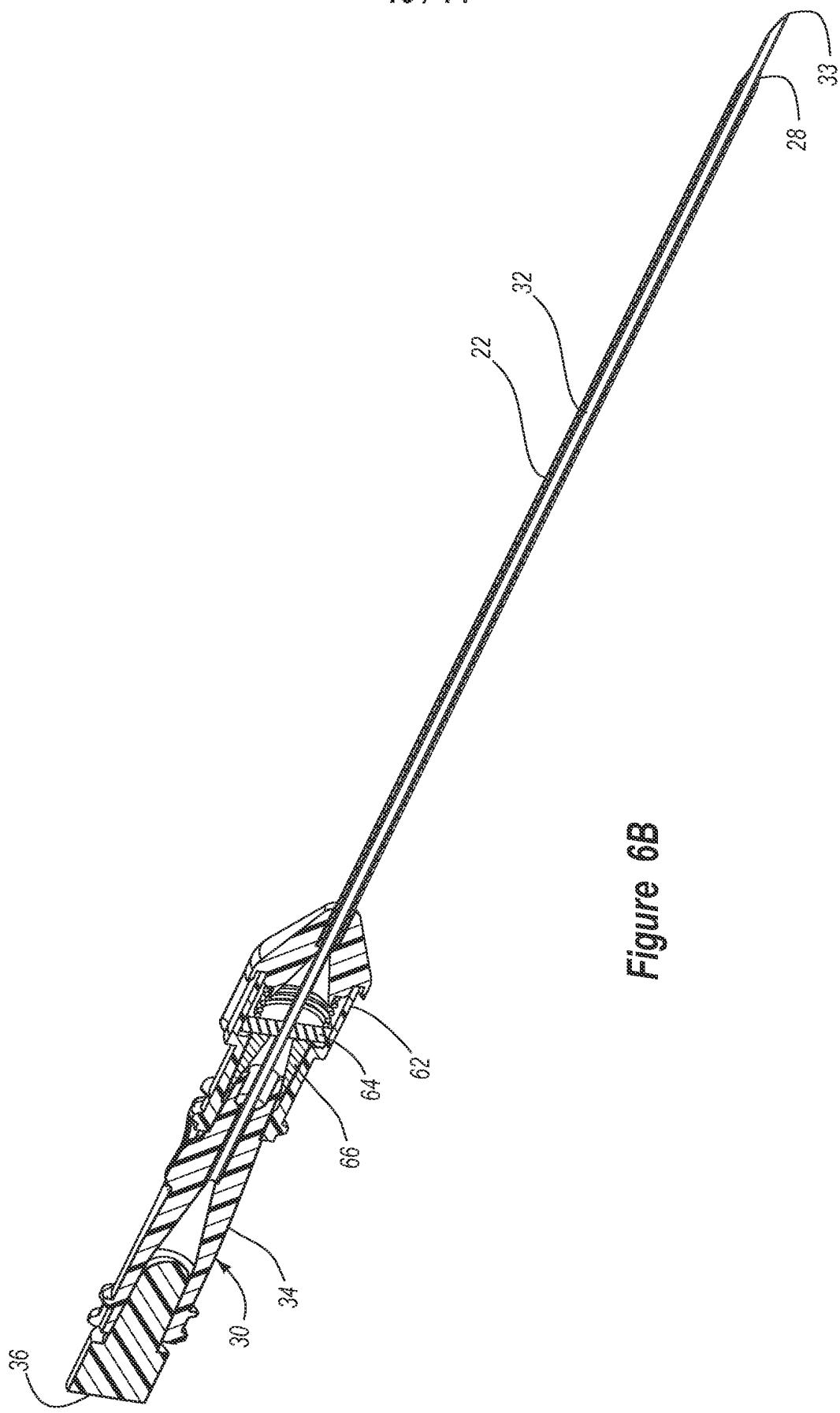


Figure 6B

14 / 14

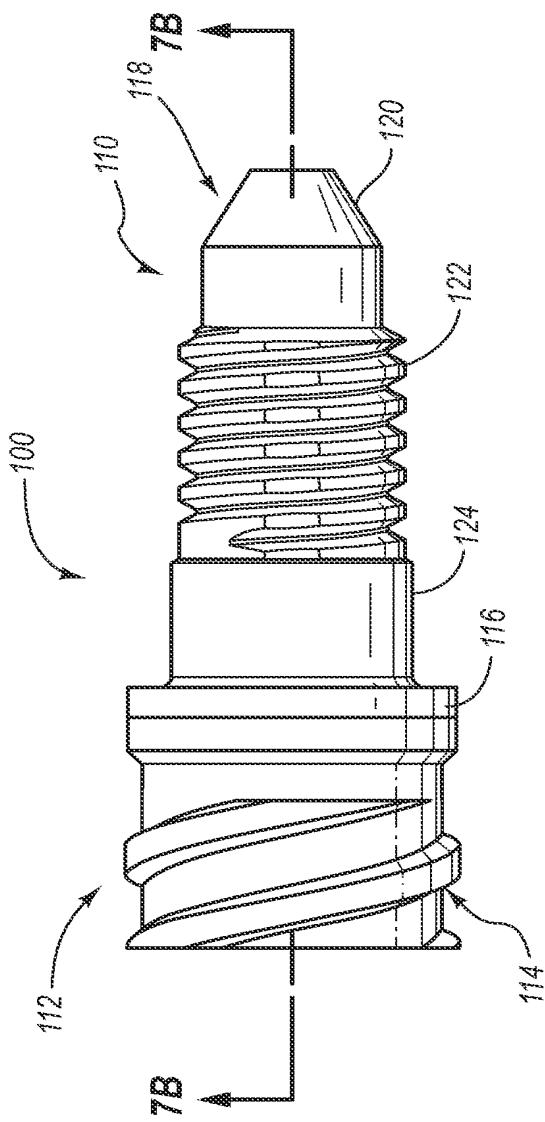


Figure 7A

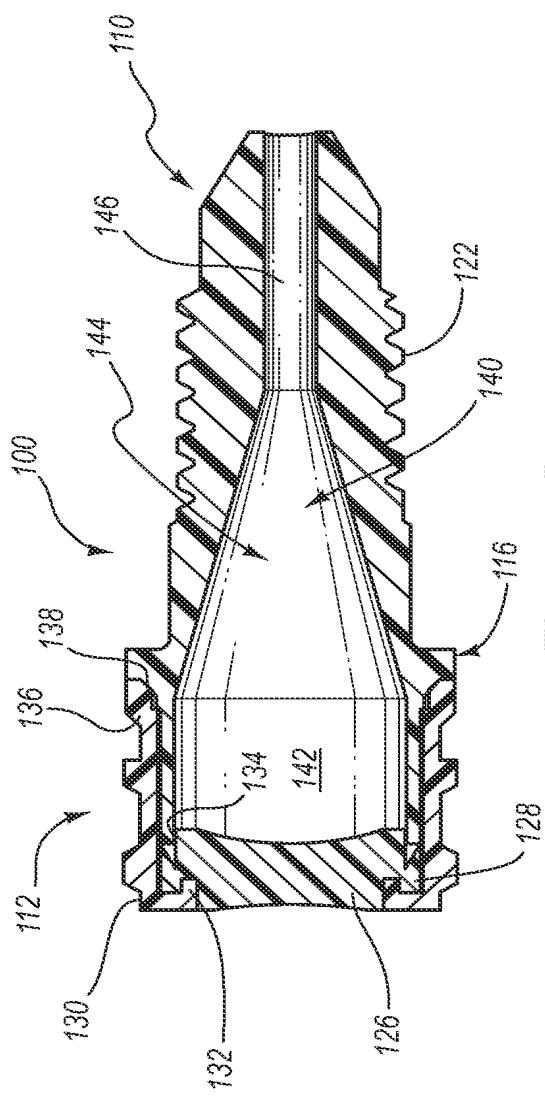


Figure 7B

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 10/23491

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 5/00 (2010.01)

USPC - 604/246

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61M 5/00 (2010.01)

USPC: 604/246

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

IPC(8): A61M 5/00 (2010.01)

USPC: 604/19, 48, 93.01, 246, 247, 249, 256, 264, 523

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Electronic Databases Searched: Google Scholar; Google Patent; PubWest (US Patents full-text, US PGPubs full-text, EPO Abstracts, and JPO Abstracts) Search Terms Used: valve, connector, bodily, body, fluids, needle, spring, seal, catheter, luer, port, drainage, male, female, slit, cannula, lumen, tapered, frusto-conical, frustro, conical

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|-----------|--|-----------------------|
| X         | US 4,143,853 A (ABRAMSON) 13 March 1979 (13.03.1979) entire document especially Fig. 1, Fig. 3, Fig. 4, Fig. 5, Fig. 6; abstract; col 2, ln 31-52; col 3, ln 32-54; col 5, ln 21-38) | 1-8                   |
| Y         |  | 9-27                  |
| Y         | US 6,651,956 B2 (MILLER) 25 November 2003 (25.11.2003) Fig. 3, Fig. 4; col 4, ln 19-55; col 7, ln 27-62  | 9-27                  |
| Y         | US 5,989,233 A (YOON) 23 November 1999 (23.11.1999) Fig. 2, Fig. 5, Fig. 6; col 6, ln 20 to col 8, ln 7  | 10-17                 |
| A         | US 7,140,592 B2 (PHILLIPS) 28 November 2006 (28.11.2006) entire document generally   | 1-27                  |
| A         | US 6,482,188 B1 (ROGERS et al.) 19 November 2002 (19.11.2002) entire document generally  | 1-27                  |
| A         | US 5,312,363 A (RYAN et al.) 17 May 1994 (17.05.1994) entire document generally  | 1-27                  |
| A         | US 5,064,416 A (NEWGARD et al.) 12 November 1991 (12.11.1991) entire document generally  | 1-27                  |

Further documents are listed in the continuation of Box C.

|   |  |
|---|--|
| * Special categories of cited documents:  |  |
| "A" document defining the general state of the art which is not considered to be of particular relevance  | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "E" earlier application or patent but published on or after the international filing date   | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "O" document referring to an oral disclosure, use, exhibition or other means  | "&" document member of the same patent family  |
| "P" document published prior to the international filing date but later than the priority date claimed  |  |

Date of the actual completion of the international search

12 April 2010 (12.04.2010)

Date of mailing of the international search report

20 APR 2010

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-3201Authorized officer:  
Lee W. Young  
PCT Helpdesk: 571-272-4300  
PCT OSP: 571-272-7774